REMARKS

Claims 1-27 are pending. Claims 15, 16, and 20-27 are withdrawn from consideration. Claims 1-14 were rejected under 35 U.S.C. § 101. Claims 1-9 and 17-19 were rejected under 35 U.S.C. § 112, first paragraph. Claims 10-14 were further rejected under 35 U.S.C. § 112, second paragraph. Claims 1-9 and 17-18 were rejected under 35 U.S.C. § 102(e). Each of these rejections is addressed below.

Support for the Amendments

Support for new claims 28 to 36, and for the amendment of claims 1, 2, 3, and 17 is found throughout the specification as originally filed. For example, support for the amendment of claims 1, 2, 3, and 17, which now recite "80% identity" is found at page 6, lines 18-20; support for new claims 29 to 36, which recite 90% or 95% identity, is found at page 6, lines 18-20; support for new claim 28 and for the amendment of claims 1, 2, 3, and 17, which now recite "the first 38 amino acids of SEQ ID NO:25," is found, for example, at page 17, lines 17-19.

Claim Objection

The Examiner objects to claims 10-14 for being drawn to non-elected subject matter. Given that claims 10-14 have been cancelled, this objection is now moot.

Rejection under 35 U.S.C. § 101

Claims 1-14 were rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter, on the grounds that the claims are directed to a peptide of natural origin. Applicants note that the claimed peptides were selected from a library of random peptides (page 14, lines 21-23). Given that such peptides were generated synthetically and are not of natural origin, this rejection should be withdrawn.

Rejections under 35 U.S.C.§ 112, first paragraph

Written Description

Claims 1-9 and 17-19, which feature claims to peptides that bind streptavidin, were rejected under 35 U.S.C.§ 112, first paragraph as lacking an adequate written description, based on the assertion that the specification fails to describe the structural and functional features of the claimed genus of peptides. As detailed below, Applicants' amended claims, which are now directed to isolated peptides that bind streptavidin and contain an amino acid sequence that has at least 80%, 90%, and 95% identity to the first 38 amino acids of SEQ ID NO:25, clearly meet the standard for an adequate written description, and this rejection should be withdrawn. Regarding the written description requirement, M.P.E.P. 2163 II A 3ii, states:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by *...disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such*

identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Applicants' current claims recite specific structural and functional characteristics that define the claimed polypeptides. With respect to the specific structural characteristics, claims 1-9 and 17-19 now require an isolated peptide having at least 80% identity to the first 38 amino acids of SEQ ID NO: 25; and new claims 29 to 36, which depend from claims 1, 2, 3, or 17, require at least 90% or 95% identity. Applicants disclose in their specification that the sequences required for high affinity binding are present in these 38 amino acids (page 29, lines 25-27). In addition, the claims require that the peptide have specific functional characteristics, i.e., the peptide is required to bind streptavidin with a specific dissociation constant. Applicants describe exemplary peptides that fall within the scope of these claims at Figure 5, demonstrating that Applicants were clearly in possession of the claimed genes. Based on this recitation of characteristic structural and functional features, the skilled artisan can plainly recognize those peptides falling within the scope of the invention as presently claimed. This is all that is required to meet the written description requirement, and this rejection should be withdrawn.

Enablement

Claims 2, 4-7, and 17-19, which are directed to streptavidin binding peptides that lack an HPQ domain, are also rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. While the Examiner acknowledges that Applicants have enabled a high-

affinity streptavidin binding peptide comprising an HPQ domain, and have enabled SB20, a peptide that lacks this domain, the Examiner asserts that claims 2, 4-7, and 17-19 lack enablement for two reasons: first, the claims fail to define a unifying characteristic for the claimed genus of peptides; and second, undue experimentation is required to practice the full scope of the claims. The Examiner cites Katz (Biochemistry 34:15421-15429, 1995, hereafter "Katz") in support of the enablement rejection.

Regarding the enablement requirement for a claimed genus, the M.P.E.P. 2164.02 states:

> For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

As detailed below, the claims clearly meet the standard of enablement and this rejection should be withdrawn.

With respect to the first reason for rejection, that the claims fail to define a unifying characteristic of the genus, the amended claims describe the claimed peptides not only by their streptavidin binding affinity, but also by their amino acid identity (e.g., 80%, 90%, 95%) to a domain that encompasses the determinants for high affinity binding to streptavidin (i.e., the first 38 amino acids of SEQ ID NO:25) (page 29, lines 25-27). Thus, this basis for the enablement rejection should be withdrawn.

In support of the second basis for the enablement rejection, that undue experimentation would be required to identify the claimed streptavidin binding peptides, the Examiner cites Katz, a reference that describes streptavidin binding cyclic peptides and linear peptides that contain an HPQ motif. Katz fails to support this basis for the enablement rejection, because Katz merely describes the binding characteristics of peptides having an HPQ domain. Katz fails to address methods of identifying peptides that lack an HPQ domain, and thus cannot be cited to support the unpredictability of such methods. This basis for the enablement rejection should also be withdrawn.

As acknowledged by the Examiner, Applicants' specification discloses the identification of an exemplary streptavidin binding peptide that lacks an HPQ motif, and discloses methods for the identification of other streptavidin binding peptides. Regarding these methods, the Examiner states:

> *The specification walks us through the steps from the generation of a streptavidin-binding peptide library to the identification of peptides binding streptavidin* (pages 21-25, for example). Most of the peptides described in the specification contain at least one HPQ motif, however, *one peptide, identified as SB20, does not contain such a domain* (see table 1, page 16-17).

Provided with Applicants' disclosure, the skilled artisan, using no more than routine methods, could predictably identify streptavidin binding peptides--whether or not they contain an HPQ motif. This is all that is required for enablement, and this rejection should be withdrawn.

Rejections under 35 U.S.C.§ 112, second paragraph

Claims 10-14 were further rejected under 35 U.S.C. § 112, second paragraph. Because these claims have been cancelled, this rejection is now moot.

Rejections under 35 U.S.C. § 102(e)

Claims 1-9 and 17-18 were rejected under 35 U.S.C.§ 102(e) as anticipated by Nolan et al., U.S. Patent No. 6,326,157. Nolan describes a biotinylated GFP fusion protein that binds streptavidin with high affinity. Nolan fails to describe a streptavidin binding protein having at least 80% homology to the first 38 amino acids of SEQ ID NO:25. Accordingly, the anticipation rejection should be withdrawn.

Conclusion

Enclosed is a Petition to extend the period for replying to the Office action for one month, to and including June 26, 2004, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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